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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,061	06/28/2003	Shaoling Li	ARC 3162 R1	6874

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EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/609,061	Applicant(s) LI ET AL.	
	Examiner Eric E. Silverman, PhD	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-63 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3-1-04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Receipt of Information Disclosure Statement, filed March 1, 2004 is acknowledged.

Claims 1 – 63 are pending in this action.

Specification

The use of various trademarks has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43, 44 and 63 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 43 and 44, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 63 requires "dry process conditions". However, the method of this claim requires the use of a suspension (see claim 61, from which instant claim depends). It is unclear how a

Art Unit: 1615

suspension, which has solvent and is therefore “wet”, can be used in a “dry process condition”, which is solvent-free. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 6, and 12 – 16 rejected under 35 U.S.C. 102(b) as being anticipated by US 6,419,952 to Wong et al.

Wong teaches a coating suspension that contains a film forming polymer, an osmapolymer, and an osmagent (col. 10, line 19 – col. 11, line 38). In specific embodiments, the film forming polymer is methyl cellulose, the osmagent is sodium chloride, and the osmapolymer is sodium carboxymethyl cellulose. These materials are mixed in a suspension containing 2,300 g water and 750 g ethanol (Example 1). The amounts of the materials are disclosed to be in the ranges of instant claims (examples 1 – 8). Note that instant ranges recite “about”. Since the term “about” is not defined in the specification, this reference anticipates instant claims in the instances where the amount of substances in the art is nearly, but not exactly, that which is recited in the claims.

Claims 45, 58 – 60 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,800,422 to Dong et al.

Dong teaches a controlled release dosage form with an osmotic barrier coating. The coating is a mixture of a barrier layer and an expanding (osmotic) layer (col. 11, lines 16 – 38).

Art Unit: 1615

When the osmotic layer portion of this layer (col. 10, line 55 – col. 11, line 4) is mixed with the barrier layer (col. 11, lines 5 – 15) in the indicated proportion (col. 11, lines 16 – 38), the resulting coating has 23 % HMPC and 24 % NaCl. Note that HPMC is the film-forming polymer, and NaCl is the osmotic agent. Dong also teaches a capsule that is coated with this coating (figures and descriptions thereof).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 – 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,419,952 to Wong et al.

Some of the teachings of Wong are discussed above.

Wong also teaches dosage forms that comprise a coating derived from the suspensions discussed above, wherein the dosage forms are capsular, and additionally comprise a semipermeable layer (claim 1, figures and descriptions thereof).

The amounts of the contents of the suspension of Wong are not exactly identical to those of instant claims. The compositions of the coatings derived from the suspensions are not taught.

Nonetheless, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to vary the amounts of the materials in the suspensions. The artisan would recognize that since the suspension is taught to be used to form coatings, optimization of the contents of the suspension is effectively optimization of the contents of the coating. Absent an unexpected result, the artisan would be motivated to do so in order to achieve the best results. For instance, the artisan would recognize that the controlled release profile (see figures 11 – 17 and descriptions thereof) will depend to a great extent on the composition of the coating. Accordingly, the artisan would be motivated to optimize the composition of the coating in order to alter the release profile. The artisan would know how to make these manipulations, and would enjoy a reasonable expectation of success in doing so. The expected result would be a suspension for coating a dosage form, the coating formed therefrom, a dosage form comprising the coating, and a method of applying the coating wherein the composition of the suspension and the coating is optimized, according to Wong.

Claims 46 – 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,800,422 to Dong et al.

The teachings of Dong are discussed above.

Dong does not teach coatings with the precise amounts of materials as instant claims.

Nonetheless, since the components of the coating of Dong are the same as those of instant claims, and since the amounts of those components are similar to those of instant claims, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to optimize the coating of Dong to arrive at the invention of instant claims. The motivation to do so would be to achieve the best possible result. For example, the artisan would realize that the release profile will depend greatly on the composition of the coating, and thus would be motivated to change the coating in order to achieve the desired release profile. Such manipulations are within the purview of the artisan, who would enjoy a reasonable expectation of success. The expected result would be a coating composition according to Dong wherein the amounts of the components are optimized.

Claims 1 – 43 and 63 are rejected under 35 U.S.C. 103(a) as being obvious over US 6,419,952 to Wong et al. in view of US 5,800,422 to Dong et al.

The teachings of Wong are discussed above.

Wong does not teach a dry coating process. Wong also does not teach amounts of the components of the coating suspension that are precisely identical to those of instant claims.

Some of the teachings of Dong are discussed above. Dong also teaches a method of providing an osmotic coating by dry granulation and compression of the granules into a coating, which is a “dry” process (Example 1, Example 3).

Accordingly, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to change the amounts of the materials in the suspension of Wong. The motivation to do so comes from Dong, who teaches coatings with these same materials, and also teaches how much of each material should be present in the coating. Since Wong’s suspensions

Art Unit: 1615

are taught to be used to form coatings, the artisan would look to the teachings of Dong to determine how much of each material should be in the final coating, and then formulate the suspension accordingly. This type of manipulation is within the ken of the skilled artisan, who would enjoy a reasonable expectation of success. Furthermore, it would be obvious to use a “dry” processing technique in forming the coating, since Dong teaches this as an exemplary embodiment of the invention. Since Dong teaches how to do this, the artisan would enjoy a reasonable expectation of success.

The expected result would be a coating suspension wherein the components were present in optimal amounts, in order to achieve a coating with the optimal amount of each component, and a process of coating a dosage form with the coating using a “dry” process.

Conclusion

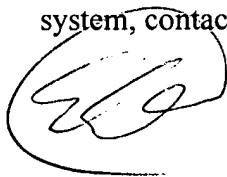
No claims are allowed. No claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

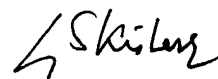
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Art Unit 1615



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